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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/734,929 | 12/12/2003 | Richard S. Ginn | 937.03 | 2257 |

8685 7590 01/05/2007
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| EXAMINER |
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ANDERSEN, MICHAEL T

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| ART UNIT | PAPER NUMBER |
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3734

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/05/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 10/734,929 | Applicant(s) GINN ET AL. | |
| | Examiner M. Thomas Andersen | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☐ Claim(s) 1-25, 27-29, 31-35 and 37 is/are rejected.
 7) ☒ Claim(s) 26, 30, 36 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/12/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgement is made of the claim to benefit of application number 09/866,548, filed on 05/25/2001.

Information Disclosure Statement

The information disclosure statement (IDS) received on 12/12/2003 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

The disclosure is objected to because of the following minor informalities: page 8, line 17, "element" should likely be inserted between the words "annular-shaped may" ; page 16, line 24, the serial number should be updated.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

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by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 11 and 19 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,663,655. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of the invention to not include a helical thread on the outer surface because the body could stay in place without such a thread.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25, 27-29, 31-35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnick, U.S. 5,320,639. Rudnick discloses a vascular plug delivery system.

Rudnick does not disclose a bioabsorbable body separate from a sealing member 18. However, Rudnick does disclose, "the plug may be provided with a more densely packed material on the outside such that complete swelling of the plug occurs after it reaches the puncture site." It would have been obvious to one having ordinary skill in the art at the time of the invention to use a bioabsorbable material separate from the plug member as the densely packed material disclosed by Rudnick because the densely packed material could be made from a different material, i.e. a material more dense than the sealing member.

With such an interpretation of Rudnick, the sealing member is considered to be numeral 18 (figure 3) that would be disposed within this densely packed material that makes up the outer bioabsorbable body. The sealing member 18 is made of an expandable material that can expand when exposed to fluid. "The plug may also be formed from a spongy or compressed material that expands upon contact with moisture

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in the body.” Rudnick, col. 4, lines 6-8. In other words, the plug may be considered an expandable gel foam.

Further, the sealing member comprises two configurations: a first sealed configuration and a second configuration accommodating a device through the lumen such as a guidewire or cannula. “The plug, once the cannula is withdrawn, tends to expand inwardly, thereby closing the central lumen in the plug and sealing the vessel.” Id., col. 6, lines 13-15.

Numerical 212 can be considered an elongate shaft extending from the proximal end of the body. Also, depending on where the body is to be implanted, it would be obvious to one having ordinary skill in the art at the time of the invention to limit the length of the body to not more than about ten millimeters so that the body won't extend out of the wound. Further, if the wound is large, it would have been obvious to one having ordinary skill in the art to have the body's diameter not more than about twice the length of the body.

The sealing member can be said to taper. See figure 3. The sealing member can be said to comprise a flexible material that is wedged into the tapered portion of the sealing member, as the sealing member itself is made up of flexible material. Further, as mentioned above, because the sealing member 18 is inside the lumen of the bioabsorbable body (densely packed material), it substantially seals the lumen from fluid flow therethrough.

Figure 3 also shows a connector for detachably securing the body to a delivery device.

The sealing member 18 can be considered a coil of material, as shown by the dark lines near numeral 18 in figure 2.

Upon delivery of the sealing member, the plug member has a cross-section larger than a cross-section of the delivery member because the sealing member expands upon fluid contact.

Numeral 24 in figure 3 is considered to be a valve connected to the sealing member.

The distal end of numeral 212 (figure 16) acts as a location indicator, and the lumen of 212 acts as a bleed back lumen.

In regard to claim 20, "a passage" is considered synonymous with the lumen described above.

Further, the sealing member can be said to comprise a valve at its proximal end as it opens and closes to allow elongate member 12 to be inserted therethrough.

Elongate member can be considered an obturator with a substantially atraumatic distal tip (figure 8). The plug member 18 is releasable from the elongate member (figure 8).

Numeral 28 can be considered a connector that connects and deploys plug member 18 in that it releasably secures the plug member to the distal end of the elongate member.

Allowable Subject Matter

Claims 26, 30 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

December 14, 2006

A handwritten signature in black ink, appearing to read "M. J. Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER